

REMARKS

Claims 1 – 34 and 38 – 49 are pending in the present application. Claims 35-37 were withdrawn from the case as being drawn to a separate invention. Claims 3, 13-26, 31-34, 46, and 49 have been withdrawn from consideration pending allowance of a generic claim as being drawn to a non-elected species. All of the pending claims have been rejected in the Office Action mailed December 31, 2002. Claim 1 is amended herein to include the limitations of Claim 2. Claims 27, 38, 41, and 44 also are amended herein.

All Pending Claims Now Comply With 35 U.S.C. § 112

In the Office Action mailed December 31, 2002, Claims 4 and 41 were rejected under 35 U.S.C. § 112 for reciting limitations lacking antecedent basis. Applicants submit that the amendments contained herein overcome this rejection and that all pending claims now fully comply with 35 U.S.C. § 112.

U.S. Patent 4,540,402 To Aigner Does Not Anticipate The Pending Claims

In the Office Action mailed December 31, 2002, Claims 1 and 2 were rejected as being anticipated by the Aigner patent. Applicants respectfully assert that Claim 1, as amended, is not anticipated by Aigner. Amended Claim 1 defines a multilumen catheter for directing the flow of blood through a patient through a single cannulation site. The catheter has a proximal end, a first distal end, and a second distal end. The catheter also has a first lumen that extends between the first distal end and the proximal end and a second lumen that extends between the second distal end and the proximal end. The catheter also has at least one aperture in one of the lumens positioned near the proximal end to maintain or enhance perfusion of blood to the patient's vasculature downstream of where the aperture resides in the vasculature when the catheter is inserted into the patient for treatment.

In contrast, Aigner discloses a double perfusion catheter that has three proximal ends. The Aigner device is designed for isolated perfusion of the liver in intraarterial chemotherapy. Aigner at Column 1, lines 4-6; see also Abstract. The Aigner device includes a splint catheter 1 and a second catheter tube 3 mounted to the splint catheter 1. See FIG. 1. A shunt tube 2 is attached to the splint catheter 1 at a location off-set from the second catheter tube 3. Id.; see also column 2, lines 6-8. A solid rod 7 can be inserted into the back end of the splint catheter 1 to

temporarily close one or more lateral openings 4 in the splint catheter 1. Column 2, lines 22-25. The back end of the splint catheter 1 forms a first proximal end of the Aigner device.

In application, the splint catheter 1 of Aigner is placed in and ligated to the vena cava, i.e., the vessel is cinched onto the splint catheter 1 from the vessel's outer surface. Column 42-45. To achieve isolated liver perfusion, the portal vein is clamped upstream of the liver. Column 3, lines 35-42. A circuit connected to the portal vein upstream of the clamp is also connected to a proximal end of the shunt tube 2, i.e., to a second proximal end of the Aigner device. This circuit conveys venous blood around the liver to the shunt tube 2. Venous blood that would otherwise be routed through the liver is conveyed to the splint catheter 1 in the vena cava. After this shunt (known as a portocaval shunt) is established, fluid can be perfused through the liver in a controlled manner. After the perfusion fluid flows through the liver, the fluid is withdrawn by the second catheter tube 3. Column 3, lines 26-31. A proximal end of the catheter tube 3, i.e., a third proximal end of the Aigner device, is connected to a heart-lung circuit. Id. Placement of the splint catheter 1 appears to be by surgical cut down, rather than through cannulation.

In further contrast to the Applicants' claimed invention, the lateral openings 4 of Aigner drain the kidneys in application. The configuration and placement of the splint catheter 1 during treatment would block the renal vein and would prevent drainage of venous blood from the kidney. Accordingly, the lateral openings 4 are provided in the splint catheter 1 to drain venous blood exiting the kidney via the renal vein. Column 3, lines 31-35. Blood drained from the kidney passes through the lateral opening 4 and is conveyed inside the splint catheter 1 toward the heart. Thus, the location of the lateral openings 4 and the configuration of the splint catheter 1 provide upstream drainage rather than downstream perfusion.

Aigner does not disclose a catheter as claimed because it does not have a first lumen that extends between a first distal end and a proximal end and a second lumen that extends between a second distal end and the proximal end. As discussed above, the Aigner device appears to have three distinct proximal ends. None of these proximal ends have more than a single lumen extending therefrom. Moreover, the three proximal end structure of the Aigner device appears to require that the Aigner device be placed via a surgical cut-down rather than via a cannulation. Furthermore, no structure is provided in the Aigner device to maintain or enhance perfusion of blood to the patient's vasculature downstream of where the structure resides in the vasculature.

Thus, for at least these reasons, the Aigner device does not teach the arrangement of amended Claim 1.

Claims 4 - 12 depend from Claim 1. As discussed above, Claim 1 is allowable as amended. Claims 4 - 12 each recite an additional unique combinations of features. Therefore, these claims are allowable in their own right and also are allowable because they depend from an allowable claim.

U.S. Patent No. 6,309,969 Is Disqualified As A Reference

The Examiner rejected Claims 27-30, 38-41, and 43 as being rendered obvious by the combination of U.S. Patent No. 4,540,402 to Aigner ("Aigner") and U.S. Patent No. 6,390,969 to Bolling et al. The Examiner also rejected Claims 1, 9, 10, 44, 45, and 47 as being rendered obvious by the combination of Aigner, Bolling et al., and U.S. Patent No. 6,083,198 to Afzal.

While the Examiner does not specify under which paragraph of 35 U.S.C. § 102 the '969 Bolling patent is cited for an obviousness rejection, Applicants assume it is cited as prior art under 35 U.S.C. § 102(e). As explained below, however, under 35 U.S.C. § 103(c), the '969 patent is not available as a reference against the present application for this rejection. Section 103(c) states in part that subject matter "which qualifies as prior art only under . . . subsections (e), (f), and (g) of section 102 . . . shall not preclude patentability under this section where the subject matter and the claimed invention were at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." This application, and the '969 Bolling patent were, at the time the invention of the present application was made, owned by the same entity. The same is true for each of U.S. Patent Nos. 6,200,260, issued March 13, 2001, 6,299,575, issued October 9, 2001, 6,387,037, issued May 14, 2002, and 6,428,464, issued August 6, 2002. Given this common ownership, Applicants specifically request that the Examiner remove the rejections based upon the '969 patent.

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Information Disclosure Statement Submitted Herewith

Each of the forgoing references not yet of record are listed in an Information Disclosure Statement submitted herewith.

Generic Claim Now In Condition For Allowance

In the *Preliminary Amendment and Response to Restriction Requirement* filed October 11, 2002, Applicants asserted that claims 1, 27, 38, and 44 are generic to the species set forth in the *Restriction Requirement* mailed September 12, 2002. As discussed above, each of these claims is in condition for allowance. Therefore, Applicants respectfully request that Claims 3, 13-26, 31-34, 46, and 49 be brought back into the case, as provided for in M.P.E.P. § 809.02(c).

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CONCLUSION

In view of the foregoing remarks, Applicants submit that the pending claims are allowable over the references of record and, therefore, request the Examiner to pass the pending claims to issuance. If there are any remaining questions or issues that may be resolved by a telephone conference, the Examiner is requested to contact the undersigned at (949) 760-0404.

Respectfully submitted,

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